UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION MDL No. 2327

(SEE ATTACHED SCHEDULE)

CONDITIONAL REMAND ORDER

The transferee court in this litigation has advised the Panel that coordinated or consolidated pretrial proceedings in the action(s) on this conditional remand order have been completed and that remand to the transferor court(s), as provided in 28 U.S.C. § 1407(a), is appropriate.

IT IS THEREFORE ORDERED that the action(s) on this conditional remand order be remanded to its/their respective transferor court(s).

IT IS ALSO ORDERED that, pursuant to Rule 10.2 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, the transmittal of this order to the transferee clerk for filing shall be stayed 7 days from the date of this order. If any party files a notice of opposition with the Clerk of the Panel within this 7−day period, the stay will be continued until further order of the Panel. This order does not become effective until it is filed in the office of the Clerk for the United States District Court for the Southern District of West Virginia.

IT IS FURTHER ORDERED that, pursuant to Rule 10.4(a), the parties shall furnish the Clerk for the Southern District of West Virginia with a stipulation or designation of the contents of the record to be remanded.

Inasmuch as no objection is pending at this time, the stay is lifted.

Feb 17, 2017

CLERK'S OFFICE
UNITED STATES
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION MDL No. 2327

SCHEDULE FOR CRO

TRANSFEREE			TRANSFEROR			
DIST	**DIV.**	**C.A.NO.**	**DIST**	**DIV.**	**C.A.NO.**	**CASE CAPTION**
WVS	2	12−00873	ILN	1	12−01801	Walker et al v. Ethicon, Inc. et al
WVS	2	12−01071	ILN	1	12−02072	Schnering et al v. Ethicon, Inc. et al
WVS	2	12−01216	ILN	1	12−02400	Wiltgen et al v. Ethicon, Inc.
WVS	2	12−01121	MOW	4	12−00383	Guinn v. Ethicon, Inc. et al

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

SHIRLEY WALKER, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-00873

ETHICON, INC., et al.,

Defendants.

ORDER AND SUGGESTION OF REMAND

Pursuant to 28 U.S.C. § 1407 and the Rules for Multidistrict Litigation promulgated thereunder, specifically Rule 10.1(b), the court suggests that this action be remanded to the United States District Court for the Northern District of Illinois. All pretrial proceedings, including discovery and dispositive and *Daubert* motion practice, are complete, and the case is ready for trial. I have attached a Suggestion of Remand Memorandum for the transferor court's reference.

Upon receipt of an order to remand from the Clerk of the Judicial Panel on Multidistrict Litigation ("MDL Panel") *and* any joint designation of the MDL 2327 record by counsel, the Clerk of this court is directed to transmit the following to the transferor court: (1) a copy of the member case docket sheet; (2) the entire file for the member case; (3) the docket sheet for MDL 2327, 2:12-md-2327; (4) all Pretrial Orders ("PTO") entered in 2:12-md-2327; and (5) any other filing from 2:12-md-2327 which the parties jointly designate. It is **ORDERED** that within seven (7) days of

the MDL Panel's transmittal of the remand order to this court, the parties shall file a joint designation of any non-PTO filings from 2:12-md-2327.

The court **DIRECTS** the Clerk to send a copy of this Order and Suggestion of Remand to the Clerk of the MDL Panel, counsel of record and any unrepresented party.

ENTER: February 6, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

SUGGESTION OF REMAND MEMORANDUM
February 6, 2017

TO: Transferor Judge
FROM: Judge Joseph R. Goodwin, Presiding Judicial Officer, Ethicon MDL, MD 2327
RE: Ethicon MDL Pelvic Mesh Case(s) transferred to your court –
***Shirley Walker, et al. v. Ethicon, Inc., et al.*, No. 2:12-00873**

I. Status of this case.

This case has been transferred to the transferor court, the United States District Court for the Northern District of Illinois, from MDL 2327 in the Southern District of West Virginia.

All pretrial proceedings, including discovery and dispositive and Daubert motion practice, are complete, and the case is ready for trial. In fact, I respectfully and strongly urge the transferor court to set this case for trial as soon as possible. While the parties may insist that further discovery or motion practice is necessary, I assure you that it is not. If the transferor court will set a firm date and not allow further delay, it will aid my efforts in this MDL. In addition, I urge the transferor court to limit the number of trial days for this trial. I limited trial in these cases to six to nine days, and this has proven more than adequate.

I refer the transferor court to my *Daubert* rulings in this case [ECF Nos. 108, 109, 110, 112, 113, 114, 115, 116, 117, 118, 120], summary judgment rulings [ECF No. 121], and rulings on motions *in limine* [ECF No. 119].

II. History of MDL 2327 and other MDLs assigned to me.

I have been assigned seven MDLs by the Judicial Panel on Multidistrict Litigation (the "MDL Panel"), including MDL 2327, *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*. In total, there are over 61,000 cases filed in the seven MDLs assigned to me, approximately 32,000 of which reside in the Ethicon MDL. These cases allege injury related to the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and/or stress urinary incontinence ("SUI").

I originally tried two of five bellwether cases. *Carolyn Lewis, et al. v. Johnson & Johnson, et al.*, No. 2:12-cv-4301 and *Jo Huskey, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-05201. In *Lewis*, I entered judgment as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure, plaintiffs appealed, and the United States Court of Appeals for the Fourth Circuit affirmed the decision. In *Huskey*, the jury returned a verdict in favor of plaintiffs in the amount of $3,270,000. Defendants appealed, and the appeal is pending before the Fourth Circuit. The other three bellwethers settled or were dismissed by the parties prior to trial. *Tonya Edwards, et al. v. Ethicon, Inc., et al.*, No. 2:12-09972; *Dianne M. Bellew v. Ethicon, Inc., et al.*, No. 2:13-cv-22473; *Brenda Lehrer v. Ethicon, Inc., et al.*, No. 2:12-08157.

In addition to trying bellwethers, I entered orders setting hundreds of additional cases (involving plaintiffs from several districts across the United States) on an expedited track for individual discovery and motion practice so that those cases, known as Ethicon Waves 1, 2, 3 and 4, could be remanded or transferred if no success is had in settlement. The instant case is one of those cases from Ethicon Wave 1. Incipient settlements exist and discussions are ongoing in many more cases. While I have been extremely patient in this process and continue to encourage those settlement discussions, I find it necessary to begin the process of remanding. In addition to the cases in Waves 1 through 4, thousands of additional cases will be identified, worked up and remanded or transferred. I note that there are approximately seventeen cases that were transferred from Illinois, and there are likely many more direct filed in the Southern District of West Virginia with proper venue in Illinois. These cases also will be worked up and remanded in the near future absent settlement. Finally, I have scheduled a trial involving approximately 30 plaintiffs from West Virginia in March, 2017.

III. Noteworthy Ruling regarding the FDA 510(k) process.

I have consistently and repeatedly ruled in all cases in this MDL and the other MDLs assigned to me that plaintiffs' claims are not preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Medical Device Amendments ("MDA") to the FDCA contain an express preemption provision. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a). The products involved in this MDL received clearance under the FDCA's 510(k) process, which, as the Supreme Court held, focuses on "equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Thus, as explained in *Lohr*, the FDCA's preemption provision does not apply to state law product liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. In addition, I further concluded that the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. *See, e.g., Cisson v. C. R. Bard, Inc.*, 86 F. Supp. 3d 510, 517 (S.D. W. Va. 2015), available at 2015 WL 566959; *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp. (Sanchez I)*, No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

The Fourth Circuit recently affirmed this court's determination that the probative value of evidence related to 510(k) clearance is substantially outweighed by its possible prejudicial impact and was properly excluded under Rule 403. *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (crediting the district court's concern that "subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it").

IV. Resources available for transferor courts on the MDL 2327 website.

There is extensive information available on the court's website at www.wvsd.uscourts.gov related to the Ethicon MDL. Specifically, all Pretrial Orders in MDL 2327 can be found at http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html.

V. Contact information for the MDL 2327 court.

Our court is ready, willing and able to assist you with any matters relating to this case or any substantive or procedural issues that may arise. Please do not hesitate to contact me or my law clerk, Kate Fife at 304-347-3199 or kate_fife@wvsd.uscourts.gov. Also, you may contact the Clerk's Office at 304-347-3000 for further assistance.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DEBRA A. SCHNERING, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-01071

ETHICON, INC., et al.,

Defendants.

ORDER AND SUGGESTION OF REMAND

Pursuant to 28 U.S.C. § 1407 and the Rules for Multidistrict Litigation promulgated thereunder, specifically Rule 10.1(b), the court suggests that this action be remanded to the United States District Court for the Northern District of Illinois. All pretrial proceedings, including discovery and dispositive and *Daubert* motion practice, are complete, and the case is ready for trial. I have attached a Suggestion of Remand Memorandum for the transferor court's reference.

Upon receipt of an order to remand from the Clerk of the Judicial Panel on Multidistrict Litigation ("MDL Panel") *and* any joint designation of the MDL 2327 record by counsel, the Clerk of this court is directed to transmit the following to the transferor court: (1) a copy of the member case docket sheet; (2) the entire file for the member case; (3) the docket sheet for MDL 2327, 2:12-md-2327; (4) all Pretrial Orders ("PTO") entered in 2:12-md-2327; and (5) any other filing from 2:12-md-2327 which the parties jointly designate. It is **ORDERED** that within seven (7) days of

the MDL Panel's transmittal of the remand order to this court, the parties shall file a joint designation of any non-PTO filings from 2:12-md-2327.

The court **DIRECTS** the Clerk to send a copy of this Order and Suggestion of Remand to the Clerk of the MDL Panel, counsel of record and any unrepresented party.

ENTER: February 6, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

SUGGESTION OF REMAND MEMORANDUM
February 6, 2017

TO: Transferor Judge
FROM: Judge Joseph R. Goodwin, Presiding Judicial Officer, Ethicon MDL, MD 2327
RE: Ethicon MDL Pelvic Mesh Case(s) transferred to your court –
***Debra A. Schnering, et al. v. Ethicon, Inc., et al.*, No. 2:12-01071**

I. Status of this case.

This case has been transferred to the transferor court, the United States District Court for the Northern District of Illinois, from MDL 2327 in the Southern District of West Virginia.

All pretrial proceedings, including discovery and dispositive and Daubert motion practice, are complete, and the case is ready for trial. In fact, I respectfully and strongly urge the transferor court to set this case for trial as soon as possible. While the parties may insist that further discovery or motion practice is necessary, I assure you that it is not. If the transferor court will set a firm date and not allow further delay, it will aid my efforts in this MDL. In addition, I urge the transferor court to limit the number of trial days for this trial. I limited trial in these cases to six to nine days, and this has proven more than adequate.

I refer the transferor court to my *Daubert* rulings in this case [ECF Nos. 123, 124, 125, 126, 128, 129, 130, 131, 132, 133], summary judgment rulings [ECF No. 135], and rulings on motions *in limine* [ECF No. 134].

II. History of MDL 2327 and other MDLs assigned to me.

I have been assigned seven MDLs by the Judicial Panel on Multidistrict Litigation (the "MDL Panel"), including MDL 2327, *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*. In total, there are over 61,000 cases filed in the seven MDLs assigned to me, approximately 32,000 of which reside in the Ethicon MDL. These cases allege injury related to the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and/or stress urinary incontinence ("SUI").

I originally tried two of five bellwether cases. *Carolyn Lewis, et al. v. Johnson & Johnson, et al.*, No. 2:12-cv-4301 and *Jo Huskey, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-05201. In *Lewis*, I entered judgment as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure, plaintiffs appealed, and the United States Court of Appeals for the Fourth Circuit affirmed the decision. In *Huskey*, the jury returned a verdict in favor of plaintiffs in the amount of $3,270,000. Defendants appealed, and the appeal is pending before the Fourth Circuit. The other three bellwethers settled or were dismissed by the parties prior to trial. *Tonya Edwards, et al. v. Ethicon, Inc., et al.*, No. 2:12-09972; *Dianne M. Bellew v. Ethicon, Inc., et al.*, No. 2:13-cv-22473; *Brenda Lehrer v. Ethicon, Inc., et al.*, No. 2:12-08157.

In addition to trying bellwethers, I entered orders setting hundreds of additional cases (involving plaintiffs from several districts across the United States) on an expedited track for individual discovery and motion practice so that those cases, known as Ethicon Waves 1, 2, 3 and 4, could be remanded or transferred if no success is had in settlement. The instant case is one of those cases from Ethicon Wave 1. Incipient settlements exist and discussions are ongoing in many more cases. While I have been extremely patient in this process and continue to encourage those settlement discussions, I find it necessary to begin the process of remanding. In addition to the cases in Waves 1 through 4, thousands of additional cases will be identified, worked up and remanded or transferred. I note that there are approximately seventeen cases that were transferred from Illinois, and there are likely many more direct filed in the Southern District of West Virginia with proper venue in Illinois. These cases also will be worked up and remanded in the near future absent settlement. Finally, I have scheduled a trial involving approximately 30 plaintiffs from West Virginia in March, 2017.

III. Noteworthy Ruling regarding the FDA 510(k) process.

I have consistently and repeatedly ruled in all cases in this MDL and the other MDLs assigned to me that plaintiffs' claims are not preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Medical Device Amendments ("MDA") to the FDCA contain an express preemption provision. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a). The products involved in this MDL received clearance under the FDCA's 510(k) process, which, as the Supreme Court held, focuses on "equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Thus, as explained in *Lohr*, the FDCA's preemption provision does not apply to state law product liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. In addition, I further concluded that the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. *See, e.g., Cisson v. C. R. Bard, Inc.*, 86 F. Supp. 3d 510, 517 (S.D. W. Va. 2015), available at 2015 WL 566959; *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp. (Sanchez I)*, No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

The Fourth Circuit recently affirmed this court's determination that the probative value of evidence related to 510(k) clearance is substantially outweighed by its possible prejudicial impact and was properly excluded under Rule 403. *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (crediting the district court's concern that "subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it").

IV. Resources available for transferor courts on the MDL 2327 website.

There is extensive information available on the court's website at www.wvsd.uscourts.gov related to the Ethicon MDL. Specifically, all Pretrial Orders in MDL 2327 can be found at http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html.

V. Contact information for the MDL 2327 court.

Our court is ready, willing and able to assist you with any matters relating to this case or any substantive or procedural issues that may arise. Please do not hesitate to contact me or my law clerk, Kate Fife at 304-347-3199 or kate_fife@wvsd.uscourts.gov. Also, you may contact the Clerk's Office at 304-347-3000 for further assistance.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

CHRISTINE WILTGEN, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-01216

ETHICON, INC., et al.,

Defendants.

ORDER AND SUGGESTION OF REMAND

Pursuant to 28 U.S.C. § 1407 and the Rules for Multidistrict Litigation promulgated thereunder, specifically Rule 10.1(b), the court suggests that this action be remanded to the United States District Court for the Northern District of Illinois. All pretrial proceedings, including discovery and dispositive and *Daubert* motion practice, are complete, and the case is ready for trial. I have attached a Suggestion of Remand Memorandum for the transferor court's reference.

Upon receipt of an order to remand from the Clerk of the Judicial Panel on Multidistrict Litigation ("MDL Panel") *and* any joint designation of the MDL 2327 record by counsel, the Clerk of this court is directed to transmit the following to the transferor court: (1) a copy of the member case docket sheet; (2) the entire file for the member case; (3) the docket sheet for MDL 2327, 2:12-md-2327; (4) all Pretrial Orders ("PTO") entered in 2:12-md-2327; and (5) any other filing from 2:12-md-2327 which the parties jointly designate. It is **ORDERED** that within seven (7) days of

the MDL Panel's transmittal of the remand order to this court, the parties shall file a joint designation of any non-PTO filings from 2:12-md-2327.

The court **DIRECTS** the Clerk to send a copy of this Order and Suggestion of Remand to the Clerk of the MDL Panel, counsel of record and any unrepresented party.

ENTER: February 6, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

SUGGESTION OF REMAND MEMORANDUM
February 6, 2017

TO: Transferor Judge
FROM: Judge Joseph R. Goodwin, Presiding Judicial Officer, Ethicon MDL, MD 2327
RE: Ethicon MDL Pelvic Mesh Case(s) transferred to your court –
***Christine Wiltgen, et al. v. Ethicon, Inc., et al.*, No. 2:12-01216**

I. Status of this case.

This case has been transferred to the transferor court, the United States District Court for the Northern District of Illinois, from MDL 2327 in the Southern District of West Virginia.

All pretrial proceedings, including discovery and dispositive and Daubert motion practice, are complete, and the case is ready for trial. In fact, I respectfully and strongly urge the transferor court to set this case for trial as soon as possible. While the parties may insist that further discovery or motion practice is necessary, I assure you that it is not. If the transferor court will set a firm date and not allow further delay, it will aid my efforts in this MDL. In addition, I urge the transferor court to limit the number of trial days for this trial. I limited trial in these cases to six to nine days, and this has proven more than adequate.

I refer the transferor court to my *Daubert* rulings in this case [ECF Nos. 128, 129, 130, 131, 132, 134, 135, 136, 137, 138, 142], summary judgment rulings [ECF No. 141], and rulings on motions *in limine* [ECF Nos. 139, 140].

II. History of MDL 2327 and other MDLs assigned to me.

I have been assigned seven MDLs by the Judicial Panel on Multidistrict Litigation (the "MDL Panel"), including MDL 2327, *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*. In total, there are over 61,000 cases filed in the seven MDLs assigned to me, approximately 32,000 of which reside in the Ethicon MDL. These cases allege injury related to the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and/or stress urinary incontinence ("SUI").

I originally tried two of five bellwether cases. *Carolyn Lewis, et al. v. Johnson & Johnson, et al.*, No. 2:12-cv-4301 and *Jo Huskey, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-05201. In *Lewis*, I entered judgment as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure, plaintiffs appealed, and the United States Court of Appeals for the Fourth Circuit affirmed the decision. In *Huskey*, the jury returned a verdict in favor of plaintiffs in the amount of $3,270,000. Defendants appealed, and the appeal is pending before the Fourth Circuit. The other three bellwethers settled or were dismissed by the parties prior to trial. *Tonya Edwards, et al. v. Ethicon, Inc., et al.*, No. 2:12-09972; *Dianne M. Bellew v. Ethicon, Inc., et al.*, No. 2:13-cv-22473; *Brenda Lehrer v. Ethicon, Inc., et al.*, No. 2:12-08157.

In addition to trying bellwethers, I entered orders setting hundreds of additional cases (involving plaintiffs from several districts across the United States) on an expedited track for individual discovery and motion practice so that those cases, known as Ethicon Waves 1, 2, 3 and 4, could be remanded or transferred if no success is had in settlement. The instant case is one of those cases from Ethicon Wave 1. Incipient settlements exist and discussions are ongoing in many more cases. While I have been extremely patient in this process and continue to encourage those settlement discussions, I find it necessary to begin the process of remanding. In addition to the cases in Waves 1 through 4, thousands of additional cases will be identified, worked up and remanded or transferred. I note that there are approximately seventeen cases that were transferred from Illinois, and there are likely many more direct filed in the Southern District of West Virginia with proper venue in Illinois. These cases also will be worked up and remanded in the near future absent settlement. Finally, I have scheduled a trial involving approximately 30 plaintiffs from West Virginia in March, 2017.

III. Noteworthy Ruling regarding the FDA 510(k) process.

I have consistently and repeatedly ruled in all cases in this MDL and the other MDLs assigned to me that plaintiffs' claims are not preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Medical Device Amendments ("MDA") to the FDCA contain an express preemption provision. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a). The products involved in this MDL received clearance under the FDCA's 510(k) process, which, as the Supreme Court held, focuses on "equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Thus, as explained in *Lohr*, the FDCA's preemption provision does not apply to state law product liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. In addition, I further concluded that the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. *See, e.g., Cisson v. C. R. Bard, Inc.*, 86 F. Supp. 3d 510, 517 (S.D. W. Va. 2015), available at 2015 WL 566959; *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp. (Sanchez I)*, No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

The Fourth Circuit recently affirmed this court's determination that the probative value of evidence related to 510(k) clearance is substantially outweighed by its possible prejudicial impact and was properly excluded under Rule 403. *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (crediting the district court's concern that "subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it").

IV. Resources available for transferor courts on the MDL 2327 website.

There is extensive information available on the court's website at www.wvsd.uscourts.gov related to the Ethicon MDL. Specifically, all Pretrial Orders in MDL 2327 can be found at http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html.

V. Contact information for the MDL 2327 court.

Our court is ready, willing and able to assist you with any matters relating to this case or any substantive or procedural issues that may arise. Please do not hesitate to contact me or my law clerk, Kate Fife at 304-347-3199 or kate_fife@wvsd.uscourts.gov. Also, you may contact the Clerk's Office at 304-347-3000 for further assistance.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

SUSAN GUINN,

Plaintiff,

v. CIVIL ACTION NO. 2:12-01121

ETHICON, INC., et al.,

Defendants.

ORDER AND SUGGESTION OF REMAND

Pursuant to 28 U.S.C. § 1407 and the Rules for Multidistrict Litigation promulgated thereunder, specifically Rule 10.1(b), the court suggests that this action be remanded to the United States District Court for the Western District of Missouri. I note that the parties jointly identified the United States District Court for the Southern District of Ohio as the proper venue for this case. All pretrial proceedings, including discovery and dispositive and *Daubert* motion practice, are complete, and the case is ready for trial. I have attached a Suggestion of Remand Memorandum for the transferor court's reference.

Upon receipt of an order to remand from the Clerk of the Judicial Panel on Multidistrict Litigation ("MDL Panel") *and* any joint designation of the MDL 2327 record by counsel, the Clerk of this court is directed to transmit the following to the transferor court: (1) a copy of the member case docket sheet; (2) the entire file for the member case; (3) the docket sheet for MDL 2327, 2:12-md-2327; (4) all Pretrial Orders ("PTO") entered in 2:12-md-2327; and (5) any other filing from 2:12-md-2327 which the parties jointly designate. It is **ORDERED** that within seven (7) days of

the MDL Panel's transmittal of the remand order to this court, the parties shall file a joint designation of any non-PTO filings from 2:12-md-2327.

The court **DIRECTS** the Clerk to send a copy of this Order and Suggestion of Remand to the Clerk of the MDL Panel, counsel of record and any unrepresented party.

ENTER: February 6, 2017

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

SUGGESTION OF REMAND MEMORANDUM
February 6, 2017

TO: Transferor Judge
FROM: Judge Joseph R. Goodwin, Presiding Judicial Officer, Ethicon MDL, MD 2327
RE: Ethicon MDL Pelvic Mesh Case(s) transferred to your court –
***Susan Guinn v. Ethicon, Inc., et al.*, No. 2:12-01121**

I. Status of this case.

This case has been transferred to the transferor court, the United States District Court for the Western District of Missourri, from MDL 2327 in the Southern District of West Virginia. I note that the parties jointly identified the United States District Court for the Southern District of Ohio as the proper venue for this case.

All pretrial proceedings, including discovery and dispositive and Daubert motion practice, are complete, and the case is ready for trial. In fact, I respectfully and strongly urge the transferor court to set this case for trial as soon as possible. While the parties may insist that further discovery or motion practice is necessary, I assure you that it is not. If the transferor court will set a firm date and not allow further delay, it will aid my efforts in this MDL. In addition, I urge the transferor court to limit the number of trial days for this trial. I limited trial in these cases to six to nine days, and this has proven more than adequate.

I refer the transferor court to my *Daubert* rulings in this case [ECF Nos. 106, 107, 108, 109, 110, 112, 113, 114, 118, 119], summary judgment rulings [ECF Nos. 116, 117], and rulings on motions *in limine* [ECF No. 115].

II. History of MDL 2327 and other MDLs assigned to me.

I have been assigned seven MDLs by the Judicial Panel on Multidistrict Litigation (the "MDL Panel"), including MDL 2327, *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*. In total, there are over 61,000 cases filed in the seven MDLs assigned to me, approximately 32,000 of which reside in the Ethicon MDL. These cases allege injury related to the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and/or stress urinary incontinence ("SUI").

I originally tried two of five bellwether cases. *Carolyn Lewis, et al. v. Johnson & Johnson, et al.*, No. 2:12-cv-4301 and *Jo Huskey, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-05201. In *Lewis*, I entered judgment as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure, plaintiffs appealed, and the United States Court of Appeals for the Fourth Circuit affirmed the decision. In *Huskey*, the jury returned a verdict in favor of plaintiffs in the amount of $3,270,000. Defendants appealed, and the appeal is pending before the Fourth Circuit. The other three bellwethers settled or were dismissed by the parties prior to trial. *Tonya Edwards, et al. v.*

Ethicon, Inc., et al., No. 2:12-09972; *Dianne M. Bellew v. Ethicon, Inc., et al.*, No. 2:13-cv-22473; *Brenda Lehrer v. Ethicon, Inc., et al.*, No. 2:12-08157.

In addition to trying bellwethers, I entered orders setting hundreds of additional cases (involving plaintiffs from several districts across the United States) on an expedited track for individual discovery and motion practice so that those cases, known as Ethicon Waves 1, 2, 3 and 4, could be remanded or transferred if no success is had in settlement. The instant case is one of those cases from Ethicon Wave 1. Incipient settlements exist and discussions are ongoing in many more cases. While I have been extremely patient in this process and continue to encourage those settlement discussions, I find it necessary to begin the process of remanding. In addition to the cases in Waves 1 through 4, thousands of additional cases will be identified, worked up and remanded or transferred. These cases also will be worked up and remanded in the near future absent settlement. Finally, I have scheduled a trial involving approximately 30 plaintiffs from West Virginia in March, 2017.

III. Noteworthy Ruling regarding the FDA 510(k) process.

I have consistently and repeatedly ruled in all cases in this MDL and the other MDLs assigned to me that plaintiffs' claims are not preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). The Medical Device Amendments ("MDA") to the FDCA contain an express preemption provision. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a). The products involved in this MDL received clearance under the FDCA's 510(k) process, which, as the Supreme Court held, focuses on "equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Thus, as explained in *Lohr*, the FDCA's preemption provision does not apply to state law product liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. In addition, I further concluded that the modest probative value of such evidence is substantially outweighed by the risk of unfair prejudice, specifically, the risk of confusing and misleading the jury. *See, e.g., Cisson v. C. R. Bard, Inc.*, 86 F. Supp. 3d 510, 517 (S.D. W. Va. 2015), available at 2015 WL 566959; *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp. (Sanchez I)*, No. 2:12-cv-05762, 2014 WL 4059214, at *15 (S.D. W. Va. Aug. 18, 2014).

The Fourth Circuit recently affirmed this court's determination that the probative value of evidence related to 510(k) clearance is substantially outweighed by its possible prejudicial impact and was properly excluded under Rule 403. *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (crediting the district court's concern that "subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a 'mini-trial' could easily inflate the perceived importance of compliance and distract the jury from the central question before it").

IV. Resources available for transferor courts on the MDL 2327 website.

There is extensive information available on the court's website at www.wvsd.uscourts.gov related to the Ethicon MDL. Specifically, all Pretrial Orders in MDL 2327 can be found at http://www.wvsd.uscourts.gov/MDL/ethicon/orders.html.

V. Contact information for the MDL 2327 court.

Our court is ready, willing and able to assist you with any matters relating to this case or any substantive or procedural issues that may arise. Please do not hesitate to contact me or my law clerk, Kate Fife at 304-347-3199 or kate_fife@wvsd.uscourts.gov. Also, you may contact the Clerk's Office at 304-347-3000 for further assistance.

Activity in Case MDL No. 2327 IN RE: Ethicon, Inc., Pelvic Repair System Products Liability Litigation CRO Final Minute Order (Clerks)
JPMLCMECF
to:
JPMLCMDECF
02/17/2017 08:38 AM
Hide Details
From: JPMLCMECF@jpml.uscourts.gov
To: JPMLCMDECF@jpml.uscourts.gov

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United States

United States Judicial Panel on Multidistrict Litigation

Notice of Electronic Filing

The following transaction was entered on 2/17/2017 at 8:38 AM EST and filed on 2/17/2017

Case Name: IN RE: Ethicon, Inc., Pelvic Repair System Products Liability Litigation
Case Number: MDL No. 2327
Filer:
Document Number: No document attached

Docket Text:
*****TEXT ONLY ENTRY*****

MINUTE ORDER - TO INVOLVED CLERKS - Conditional Remand Order Finalized on 2/17/17. Please see pleading (7 in ILN/1:12-cv-01801, 7 in ILN/1:12-cv-02072, 7 in ILN/1:12-cv-02400, [2678] in MDL No. 2327, 7 in MOW/4:12-cv-00383).

A copy of the transferee court's Suggestion of Remand from the transferee court is attached to the Conditional Remand Order.

As stipulated in Rule 10.2(b) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, transmittal of the order has been stayed 7 days to give any party an opportunity to oppose the remand. The 7-day period has now elapsed, no opposition was received, and the order is directed to you for filing.

The order was entered pursuant to 28 U.S.C. 1407(a) which provides that each action so transferred by the Panel shall be remanded by the Panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred. Parties are to furnish S.D. West Virginia with a stipulation or designation of the contents of the record to be remanded and all necessary copies of any pleading or other matter filed to comply with the remand order.

Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-

02400, MOW/4:12-cv-00383 (dn)

Case Name: Schnering et al v. Ethicon, Inc. et al
Case Number: ILN/1:12-cv-02072
Filer:
Document Number: No document attached

Docket Text:
*****TEXT ONLY ENTRY*****

MINUTE ORDER - TO INVOLVED CLERKS - Conditional Remand Order Finalized on 2/17/17. Please see pleading (7 in ILN/1:12-cv-01801, 7 in ILN/1:12-cv-02072, 7 in ILN/1:12-cv-02400, [2678] in MDL No. 2327, 7 in MOW/4:12-cv-00383).

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Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Guinn v. Ethicon, Inc. et al
Case Number: MOW/4:12-cv-00383
Filer:
Document Number: No document attached

Docket Text:
*****TEXT ONLY ENTRY*****

MINUTE ORDER - TO INVOLVED CLERKS - Conditional Remand Order Finalized on 2/17/17. Please see pleading (7 in ILN/1:12-cv-01801, 7 in ILN/1:12-cv-02072, 7 in ILN/1:12-cv-02400, [2678] in MDL No. 2327, 7 in MOW/4:12-cv-00383).

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Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Wiltgen et al v. Ethicon, Inc.
Case Number: ILN/1:12-cv-02400
Filer:
Document Number: No document attached

Docket Text:
*****TEXT ONLY ENTRY*****

MINUTE ORDER - TO INVOLVED CLERKS - Conditional Remand Order Finalized on 2/17/17. Please see pleading (7 in ILN/1:12-cv-01801, 7 in ILN/1:12-cv-02072, 7 in ILN/1:12-cv-02400, [2678] in MDL No. 2327, 7 in MOW/4:12-cv-00383).

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Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Walker et al v. Ethicon, Inc. et al
Case Number: ILN/1:12-cv-01801
Filer:
Document Number: No document attached

Docket Text:
*****TEXT ONLY ENTRY*****

MINUTE ORDER - TO INVOLVED CLERKS - Conditional Remand Order Finalized on 2/17/17. Please see pleading (7 in ILN/1:12-cv-01801, 7 in ILN/1:12-cv-02072, 7 in ILN/1:12-cv-02400, [2678] in MDL No. 2327, 7 in MOW/4:12-cv-00383).

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Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

No public notice (electronic or otherwise) sent because the entry is private

Activity in Case MDL No. 2327 IN RE: Ethicon, Inc., Pelvic Repair System Products Liability Litigation Finalized Conditional Remand Order
JPMLCMECF
to:
JPMLCMDECF
02/17/2017 08:38 AM
Hide Details
From: JPMLCMECF@jpml.uscourts.gov
To: JPMLCMDECF@jpml.uscourts.gov

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United States

United States Judicial Panel on Multidistrict Litigation

Notice of Electronic Filing

The following transaction was entered on 2/17/2017 at 8:37 AM EST and filed on 2/17/2017
Case Name: IN RE: Ethicon, Inc., Pelvic Repair System Products Liability Litigation
Case Number: MDL No. 2327
Filer:
Document Number: 2678

Docket Text:
CONDITIONAL REMAND ORDER FINALIZED (re: pldg. (5 in ILN/1:12-cv-01801, 5 in ILN/1:12-cv-02072, 5 in ILN/1:12-cv-02400, [2654] in MDL No. 2327, 5 in MOW/4:12-cv-00383)) - 4 action(s) - Inasmuch as no objection is pending at this time, the stay is lifted.

Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

(Attachments: # (1) Suggestion of Remand (ILN 12-1801), # (2) Suggestion of Remand (ILN 12-2072), # (3) Suggestion of Remand (ILN 12-2400), # (4) Suggestion of Remand (MOW 12-383))

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Guinn v. Ethicon, Inc. et al
Case Number: MOW/4:12-cv-00383
Filer:
Document Number: 7

Docket Text:
CONDITIONAL REMAND ORDER FINALIZED (re: pldg. (5 in ILN/1:12-cv-01801, 5 in ILN/1:12-cv-02072, 5 in ILN/1:12-cv-02400, [2654] in MDL No. 2327, 5 in MOW/4:12-cv-00383)) - 4 action(s) - Inasmuch as no objection is pending at this time, the stay is lifted.

Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

(Attachments: # [1] Suggestion of Remand (ILN 12-1801), # [2] Suggestion of Remand (ILN 12-2072), # [3] Suggestion of Remand (ILN 12-2400), # [4] Suggestion of Remand (MOW 12-383))

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Wiltgen et al v. Ethicon, Inc.
Case Number: ILN/1:12-cv-02400
Filer:
Document Number: 7

Docket Text:
CONDITIONAL REMAND ORDER FINALIZED (re: pldg. (5 in ILN/1:12-cv-01801, 5 in ILN/1:12-cv-02072, 5 in ILN/1:12-cv-02400, [2654] in MDL No. 2327, 5 in MOW/4:12-cv-00383)) - 4 action(s) - Inasmuch as no objection is pending at this time, the stay is lifted.

Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

(Attachments: # [1] Suggestion of Remand (ILN 12-1801), # [2] Suggestion of Remand (ILN 12-2072), # [3] Suggestion of Remand (ILN 12-2400), # [4] Suggestion of Remand (MOW 12-383))

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Walker et al v. Ethicon, Inc. et al
Case Number: ILN/1:12-cv-01801
Filer:
Document Number: 7

Docket Text:
CONDITIONAL REMAND ORDER FINALIZED (re: pldg. (5 in ILN/1:12-cv-01801, 5 in ILN/1:12-cv-02072, 5 in ILN/1:12-cv-02400, [2654] in MDL No. 2327, 5 in MOW/4:12-cv-00383)) - 4 action(s) - Inasmuch as no objection is pending at this time, the stay is lifted.

Signed by Clerk of the Panel Jeffery N. Luthi on 2/17/2017.

(Attachments: # [1] Suggestion of Remand (ILN 12-1801), # [2] Suggestion of Remand (ILN 12-2072), # [3] Suggestion of Remand (ILN 12-2400), # [4] Suggestion of Remand (MOW 12-383))

Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

Case Name: Schnering et al v. Ethicon, Inc. et al
Case Number: ILN/1:12-cv-02072
Filer:
Document Number: 7

Docket Text:
CONDITIONAL REMAND ORDER FINALIZED (re: pldg. (5 in ILN/1:12-cv-01801, 5 in ILN/1:12-cv-02072, 5 in ILN/1:12-cv-02400, [2654] in MDL No. 2327, 5 in MOW/4:12-cv-00383)) - 4 action(s) - Inasmuch as no objection is pending at this time, the stay is lifted.

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Associated Cases: MDL No. 2327, ILN/1:12-cv-01801, ILN/1:12-cv-02072, ILN/1:12-cv-02400, MOW/4:12-cv-00383 (dn)

MDL No. 2327 Notice has been electronically mailed to:

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MDL No. 2327 Notice will not be electronically mailed to:

MOW/4:12-cv-00383 Notice has been electronically mailed to:

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MOW/4:12-cv-00383 Notice will not be electronically mailed to:

ILN/1:12-cv-02400 Notice has been electronically mailed to:

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ILN/1:12-cv-02400 Notice will not be electronically mailed to:

ILN/1:12-cv-01801 Notice has been electronically mailed to:

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ILN/1:12-cv-01801 Notice will not be electronically mailed to:

ILN/1:12-cv-02072 Notice has been electronically mailed to:

Christy D. Jones christy.jones@butlersnow.com, MDL200MotionFilings@butlersnow.com, MOMullan@RIKER.com, ashley.lampkin@butlersnow.com, brandy.pitts@butlersnow.com, catherine.mason@butlersnow.com, ecf.notices@butlersnow.com, kcrawford@riker.com, mkabbash@riker.com

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The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP JPMLStamp_ID=1090522767 [Date=2/17/2017] [FileNumber=718889-0] [7f17a91b4a781e83395f19d7acc5471f87a741f58285dc809cf3fba578e4cb4b56c84 8e9949aab31e705bd5cee5d59db5d1f475c4b31fd14e6908b9f62bf7d15]]

Document description: Suggestion of Remand (ILN 12-1801)
Original filename:n/a
Electronic document Stamp:
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Document description: Suggestion of Remand (ILN 12-2072)
Original filename:n/a
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Document description: Suggestion of Remand (ILN 12-2400)
Original filename:n/a
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Document description: Suggestion of Remand (MOW 12-383)
Original filename:n/a
Electronic document Stamp:
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